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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,627	12/14/2001	William M. Switzer	14114.0331US2	5188

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EXAMINER	
HILL, MYRON G	
ART UNIT	PAPER NUMBER
1648	8

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,627	SWITZER ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1- 12* is/are pending in the application.

4a) Of the above claim(s) *12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1- 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that claims are drawn to a genus, that 9- 11 relate to the method of claim 7, the method of claim 12 (group IX) should be rejoined, and that the Office should search all sequences because of the "10 sequence rule". This is not found persuasive because claim 1 is drawn to a spumavirus isolated from a human and page 10 last paragraph identifies the sequences and some are not isolated from a human. Furthermore, the policy of the Office at this time is to examine one sequence per application. The methods of Group VII (claims 9- 11) are rejoined because they share the special technical feature of the method in claim 7. In 371 applications, the invention is considered the first product and first method of use (a method of making was not claimed) when there is no lack of unity.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1- 11 and SEQ ID #1 are under consideration in this action.

Information Disclosure Statement

A signed and initialed copy of IDS paper #4 is enclosed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1- 11 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the said claims. The specification does not provide a repeatable method for obtaining the inventive spumavirus,and it does not appear to be readily available material. Deposit of virus would satisfy the enablement requirements of 35 U.S.C. 112. Applicant's deposit statement on specification page 18, lines 18 and 19 , does not indicate the extent of public availability.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that **all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent**, would satisfy the deposit requirements. See 37 CFR 1.808.

Claims 3- 6 and 7- 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to a virus with an insert and a method of killing

dividing cells, *in vivo* and *in vitro* with the virus of the invention as well as inhibiting tumor formation or growth.

Instant claims are evaluated for scope of enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in In re Wands, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

In the instant case, the instant specification is not-enabled for any methods for killing dividing cells or viruses with heterologous inserts.

Page 17, lines 20 and 21, and page 18, line 14 state that the isolated virus of the deposit, SFVHu-6 does not cause disease. The virus is as isolated and contains no modifications. The specification provides examples on RT assays, and that the virus was not spread to infected persons partner (examples 1- 3).

Since the inventive virus does not cause disease in humans and humans contain dividing cells, it is not clear how the same virus can not cause disease in one subject and kill dividing cells in another. Schenk is provided as evidence that the foamy viruses are complex and have specific requirements in there genome to be infectious and that certain functions must be maintained. However, there is no evidence or guidance or directions how the mutant viruses with heterologous inserts can be made. Also, there is no evidence or guidance or directions how the virus kills dividing cells or is effective

against tumors or other related diseases (page 8, line 21 to page 9, line14) as recited in instant claims. The specification discloses a virus **could** be made that only binds to certain receptors (page 18, line 1) and that viruses **may** be administered for cancer treatment (page 18, line 8). The enabling disclosure is clearly not commensurate in scope with these claims. There is no teaching on how specific recombinant viruses would be made, what inserts would be useful therapeutically or that the treatments are effective. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make viruses with modifications and to use the inventive virus with or without modifications commensurate in scope of the methods as claimed. Clearly there is lack of guidance directing a skilled artisan to practice the instantly claimed methods. Without specific guidance or direction and /or working examples, one of ordinary skill in the art would not be able to reproducibly practice the entire scope of the invention as claimed, without undue experimentation.

Claims 3- 6 and 7- 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a virus with an insert and a method of killing dividing cells, *in vivo* and *in vitro* with the virus of the invention as well as inhibiting tumor formation or growth.

The burden of the written description requirement in this application of a SFVHu-6 with an insert and a method of killing dividing cells, *in vivo* and *in vitro* with the SFVHu-6 of the invention as well as inhibiting tumor formation or growth has not been met.

The written description in this case only sets forth SFVHu-6.

Vas-Cath Inc. v. Mahurkar ((CAFC, 1991) 19 USPQ2d 1111), clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See Vas-Cath at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). It is respectfully submitted that the instant specification, in fact, clearly states a virus **could** be made that only binds to certain receptors (page 18, line 1). Accordingly, there is evidence that the full scope of viruses of the claimed invention was not in Applicant's possession as of the filing date sought.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see Vas-Cath at page 1115).

With the exception of SFVHu-6, the skilled artisan cannot envision the encompassed viruses and methods of use and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is

part of the invention and a reference to viruses that can express certain inserts or have particular functions *in vitro* or *in vivio* of the instant specification. See Fiers v. Revel, ((CAFC, 1993) 25 USPQ 2d 1601) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,((CAFC, 1991) 18 USPQ2d 1016).

Therefore only SFVHu-6, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

Conclusion

No claim is allowed. Applicant is reminded to remove non-elected sequences from claim 1. Sequence 1 is free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James C. Housel

JAMES HOUSEL 6/30/03
SUPERVISORY PATENT EXAMINER
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